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Long Saphenous Vein Stripping and Quality of Life – a Randomised Trial

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Objectives: *to assess the quality of life of patients undergoing sapheno-femoral junction (SFJ) ligation and long saphenous vein stripping (LSV), using two different techniques.*
Design: *prospective, randomised trial.*
Materials and methods: *eighty patients were recruited and randomised to either Perforate Invagination (PIN) stripping (43) or Conventional stripping (37). Patients completed the Short Form 36 (SF-36) and EuroQol (EQ) questionnaires preoperatively, and postoperatively at 6 weeks and 6 months.*
Results: *bodily pain, role function and physical summary were significantly improved at 6 months in the PIN stripping group. In the Conventional group, bodily pain and physical function were similarly improved, but not role function. EQ global quality of life was significantly and progressively improved at 6 weeks and 6 months in the PIN group (global score* $p<0.003$*; self-rated score* $p<0.001$*). In the Conventional group there was no overall improvement in global score or self-rated health.*
Conclusions: *primary varicose vein surgery is associated with significant and progressive improvements in quality of life scores. Whilst overall quality of health does improve in the Conventional group, this appears to be to a lesser extent than in the PIN group.*

Key Words: Quality of life; Varicose vein surgery; Long saphenous vein stripping; Randomised trial.

Introduction

Large numbers of patients undergo varicose vein surgery in the NHS per year. It is essential to adopt cost-effective methods, which are successful both clinically and from the patients' perspective. Therefore it is important to determine the patients' evaluation of the outcome of surgery, especially when alternative techniques are available.

Giving consideration to subjective accounts of health has also become important when assessing interventions and allocating resources. Different methods of quality of life analysis can be applied when measuring the impact of disease upon the patient. This data can be used to evaluate and compare both new and existing treatments.

The SF-36 questionnaire is an easy to use valid and reliable measure of health status.[1,2] It is a generic tool that can be used to investigate a wide range of diseases as it examines a broad aspect of health. The patient's health profile scores are calculated across a range of domains such as physical functioning, social functioning and bodily pain. It has previously been used to support the surgical treatment of varicose veins.[3]

The EuroQol questionnaire comprises five brief domains including mobility, self-care, usual activities, pain/discomfort and anxiety/depression. It also provides a single index health score and a patient reported assessment of their own health. It is a standardised and non-disease specific quality of life tool.[4] Previous studies have shown it to be valid, reliable and easy to use.[5,6]

The aim of this study was to compare changes in quality of life between patients undergoing PIN (PIN, Credenhill Ltd, Derbyshire, U.K.) stripping with Conventional (Astratech AB, Sweden) stripping in the surgical management of primary varicose veins. Perioperative and early clinical follow-up of these patients has been previously reported.[7] In this randomised study, comparing PIN and Conventional surgery there was shown to be no significant difference between groups in terms of operation time, length of vein stripped and area of bruising. However, the size of the exit site was significantly smaller in the PIN group. There have been no quality of life studies examining the effect of these two interventions.

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Materials and Methods

This prospective, randomised trial was undertaken at a dedicated vascular surgery unit in a University Teaching Hospital where Ethics Committee approval was obtained.

The size of the sample for the study was decided on the basis of a power calculation. This was based on the expected change in the short form-36 domain of bodily pain as changes in this domain were felt most likely to be sensitive to the effect of each PIN stripper on quality of life parameters. Normative data from the Oxford Health Life Survey 1991/2, HSRU, Oxford, was used. The SF-36 pain score (mean and (standard deviation)) of 1596 patients who consulted their GP in the last 2 weeks was 67.7 (27.6). The corresponding score of 7245 patients who did not consult their GP in the last 2 weeks was 84.6 (18.8). This degree of difference in pain score was considered significant for the purpose of our study and the data used in the power calculation as follows. Mean 1 = 84.6; mean 2 = 67.7; standard deviation (the mean of both standard deviations) = 23.2; alpha = 0.05; power 80%; two-sided p test. The size of each sample is then 30.

Eighty patients were recruited preoperatively from the venous outpatient's clinic. They had time to read and discuss the patient information sheet before informed consent was given. The group comprised 52 women with a median age of 41 years (range 23–70 years) and 28 men, median age 56 years (range 22–70). All had primary varicosities secondary to saphenofemoral junction incompetence and LSV reflux, which was confirmed in all cases by Duplex ultrasound scanning. Each of the patients completed the SF-36 and EuroQol questionnaires.

The patients were randomised to either PIN stripping (43 patients) or Conventional stripping (37 patients) using computer generated random numbers. The surgeons were informed of which procedure to use in theatre immediately before stripping took place.

The SF-36 and EuroQol questionnaires were completed again at 6 weeks and 6 months postoperatively during follow-up clinic visits.

All operations were carried out under general anaesthesia. In both methods the sapheno-femoral junctions were exposed, tributaries divided between ties and a flush ligation performed. In the Conventional group a standard stripper was passed down the long saphenous vein and its narrow end retrieved at the level of the knee. With an olive attached to the other end the vein was stripped downwards to emerge at the exit site. In the PIN group a PIN stripper was passed down the long saphenous vein and the tapered end of the stripper was manoeuvred so as to perforate the vein and tent up the skin at the level of the knee. A strong silk suture was then tied to the upper end of the stripper according to the manufacturer's recommendations and stripping performed so as to invaginate the vein.

Statistics

The data were analysed using the Mann–Whitney U-test and the Wilcoxon signed ranks test. A p value <0.05 was considered to be statistically significant.

The Bonferroni correction was used with a threshold for significance taken as 0.0051 on the basis that analysis of SF-36 data comparing 6 weeks with preop requires 10 independent null hypotheses to be tested. Therefore the threshold to keep the overall risk of type 1 error equal to 0.05 is 0.0051. Subsequent comparison of 6 months with preop is not independent of the preceding analysis so a higher threshold was not felt to be required. When the Bonferroni correction is applied to EuroQol data then the threshold for significance becomes 0.0073, reflecting the 7 hypotheses (5 domains plus overall score and self-rated score) tested.

Effect size is a recognised statistic for determining the difference between quality of life scores gained on separate occasions as recommended by Kazis *et al.*[8] It is a method of evaluating the sensitivity of quality of life measurements to important clinical change and is calculated by dividing the mean change in score by the baseline standard deviation. An effect size of 1.00 is equivalent to a change of one standard deviation in the sample. As a rule, an effect size of 0.2 is regarded as small, 0.5 as moderate and 0.8 as large.

Results

PIN group

Of the PIN group, 42 out of 43 (98%) completed the pre questionnaire, 39 out of 43 (91%) completed 6 week and 6 month follow-up questionnaires (2 did not attend (DNA), 2 left the study as they no longer wanted to participate).

Conventional group

Of the Conventional group, 36 out of 37 (97%) completed a pre questionnaire, 31 out of 37 (83%) a 6 week

Table 1. PIN group SF-36 scores. Figures in bold type are significant at $p<0.0051$.

Domain	Pre-op median (IQR)	6 weeks post-op median (IQR)	6 months post-op median (IQR)	6 weeks post-op compared to pre-op	6 months post-op compared to pre-op
				p value	*p* value
Physical function	85 (60–94)	85 (65–90)	95 (75–100)	0.761	0.014
Role function	75 (0–100)	75 (19–100)	100 (31–100)	0.431	**0.004**
Bodily pain	51 (41–74)	62 (52–74)	100 (76–100)	0.08	**<0.0001**
General health	67 (56–82)	77 (61–87)	72 (57–78)	0.091	0.347
Vitality	50 (45–69)	60 (50–70)	65 (55–75)	0.451	0.025
Social function	75 (62–100)	87 (62–100)	100 (75–100)	0.41	0.007
Role emotional	100 (58–100)	100 (67–100)	100 (100–100)	0.407	0.009
Mental health	72 (60–76)	76 (60–88)	80 (64–84)	0.107	0.009
Physical summary	45 (36–53)	45 (37–50)	55 (44–58)	0.989	**0.001**
Mental summary	50 (42–54)	53 (47–56)	53 (48–57)	0.061	0.044

IQR: Interquartile range.

Table 2. Conventional group SF-36 scores. Figures in bold type are significant at $p<0.0051$.

Domain	Pre-op median (IQR)	6 weeks post-op median (IQR)	6 months post-op median (IQR)	6 weeks post-op compared to pre-op	6 months post-op compared to pre-op
				p value	*p* value
Physical function	80 (62–90)	85 (76–99)	95 (79–100)	0.044	0.019
Role function	100 (25–100)	75 (0–100)	100 (94–100)	0.081	0.119
Bodily pain	62 (41–84)	72 (41–96)	100 (69–100)	0.949	**0.001**
General health	72 (53–79)	68 (57–87)	77 (64–82)	0.452	0.046
Vitality	55 (50–70)	68 (46–79)	70 (55–80)	0.855	0.085
Social function	87 (62–100)	87 (62–100)	100 (75–100)	0.948	0.17
Role emotional	100 (67–100)	100 (33–100)	100 (100–100)	0.647	0.386
Mental health	76 (60–88)	80 (60–91)	84 (73–92)	0.749	0.017
Physical summary	48 (33–55)	48 (37–55)	56 (46–58)	0.845	**0.003**
Mental summary	51 (48–57)	54 (45–58)	56 (51–58)	0.766	0.258

IQR: Interquartile range.

follow-up questionnaire (3 DNA, 2 missing questionnaires from the patients' case notes (MD) and 1 left), and 30 out of 37 (81%) a 6 month follow-up questionnaire (2 DNA, 2 MD, 2 left and 1 lost to follow-up).

SF-36: Comparison of PIN vs Conventional stripping

An intergroup analysis of the PIN group and Conventional group SF-36 scores were compared at the pre-intervention stage, and at 6 weeks and 6 months postoperatively using the Mann–Whitney *U*-test. There were no significant differences in quality of life scores between the two groups at any stage (Tables 1, 2).

SF-36: Effect of time

An intragroup analysis of the SF-36 scores for PIN group (Table 1, columns 5 and 6) and the Conventional group (Table 2, columns 5 and 6) was carried out using the Wilcoxon signed ranks test. Both groups show improvements in quality of life scores throughout the study period.

Health domains: Subanalysis (Table 1, columns 5 and 6)

Considering the PIN group, the domains of role function, bodily pain and physical summary were significantly improved at 6 months. In the Conventional group, bodily pain and physical function, but not role function, were significantly improved.

EuroQol: Comparison of PIN vs Conventional

The EuroQol scores of the two groups were compared preoperatively, 6 weeks postoperatively and 6 months postoperatively using the Mann–Whitney *U*-test. No statistically significant differences were found between the two groups.

Table 3. Intragroup analysis of the PIN group by effect size.

Domain	6 weeks post-op compared to pre-op by ES	6 months post-op compared to pre-op by ES
Physical function	0.085	0.296*
Role function	−0.155	0.406*
Bodily pain	0.256*	1.001***
General health	0.199*	0.107
Vitality	0.167	0.41*
Social function	0.147	0.419*
Role emotional	0.121	0.429*
Mental health	0.243*	0.479*
Physical summary	−0.049	0.607**
Mental summary	0.259*	0.424*

ES, effect size; * small change = 0.20; ** moderate change = 0.50; *** large change = 0.80.

Table 4. Intragroup analysis of the Conventional group by effect size.

Domain	6 weeks post-op compared to pre-op by ES	6 months post-op compared to pre-op by ES
Physical function	0.234*	0.319*
Role function	−0.407	0.369*
Bodily pain	0.038	0.762**
General health	0.161	0.378*
Vitality	0.104	0.313*
Social function	0.566**	0.155*
Role emotional	−0.057	0.241*
Mental health	−0.061	0.186
Physical summary	0.075	0.54**
Mental summary	−0.081	0.091

ES, effect size; * small change = 0.20; ** moderate change = 0.50; *** large change = 0.80.

EuroQol: Effect of time in the PIN and Conventional groups

The EuroQol global quality of life score showed a significant and progressive improvement at 6 weeks and 6 months for the PIN group (Table 5). In the Conventional group there was no overall improvement in global score.

At 6 months the PIN group showed a large change in effect size for bodily pain compared to the preoperative scores. There were small changes in all other domains, except general health where there was no change. The Conventional group showed a moderate change in bodily pain and physical summary at 6 months. There were small changes for all of the other domains, except mental health and mental summary where there were no changes (Tables 5 and 6).

Discussion

There is debate as to which is the best method to strip the LSV. The Conventional stripper has been criticised for its potential to cause tissue trauma as the olive head is pulled along the subcutaneous tissues of the leg.[9] In contrast, the PIN method inverts the vein and may therefore cause less tissue trauma by making a stripping channel of smaller diameter. This may lead to a difference in amount of wound haematoma and postoperative pain. A previous paper compared these two techniques in terms of time taken to strip the vein, length of vein stripped, size of the exit wound and area of resultant bruising. There was no difference between the two techniques except that the PIN method gave a slightly smaller exit site and it could be argued that its use was more cost-effective.[7] However, no assessment of pain was made in that study.

This study compared changes in health-related quality of life before and after surgery. By using the EuroQol and SF-36 health-related quality of life questionnaires we hoped to provide a further evaluation of these two techniques in terms of their impact on different domains of health.

There were no statistically significant differences between the quality of life scores of the PIN and Conventional groups at either the preoperative, 6 week or 6 month postoperative intervals. Even though a power calculation was used this may represent a type two error. However, it should be emphasised that at the end of the 6 month follow-up period the overall health had improved significantly for both groups. The PIN group showed some significant improvements for both SF-36 and EuroQol scores. Three SF-36 domains (role function, bodily pain and physical summary)

Table 5. EuroQol global quality of life score as median (interquartile range) for PIN and Conventional groups. Figures in bold type are significant at $p<0.0073$.

	Pre-op	6 weeks	6 months
PIN	0.73 (0.66–0.83)	0.8 (0.73–1.0)	1.0 (0.73–1.0)
p-value compared to pre-op		0.009	**0.003**
Conventional	0.8 (0.69–1.0)	0.83 (0.69–1.0)	1.0 (0.69–1.0)
p-value compared to pre-op		0.163	0.28

achieved significance in the PIN group whereas only bodily pain and physical summary were significant in the Conventional group. The EuroQol scores also continued to improve postoperatively. Although there were no statistically significant differences between the PIN and Conventional groups, the changes that occur within the groups through time are clear and important.

The overall results suggest that the PIN group may be more successful in terms of a greater increase in the patients' quality of life, which could be related to the smaller diameter of the stripping track and the smaller exit wound.[7] The study may have gained from the use of a more sensitive disease-specific questionnaire, such as the Aberdeen Varicose Veins questionnaire which has been adopted for use in future studies.[10]

The differences in quality of life between PIN and Conventional groups as measured in this study may influence the choice of technique adopted by surgeons. No conclusions about cost-effectiveness can be inferred from the data, but as the PIN stripper and its retrieval device can be re-sterilised, it could be cheaper to use than a disposable Conventional stripper.[7]

In conclusion, primary varicose vein surgery is associated with progressive and significant improvements in quality of life for the patients. Whilst the overall quality of health does improve in both groups, this occurs to a greater extent in the PIN group. We would be interested to see if other centres could reproduce these results and whether a study of cost-effectiveness bears out any differences in the techniques.

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